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**Nivolumab (NIVO) + ipilimumab (IPI) versus platinum-doublet chemotherapy (chemo) as first-line (1L) treatment for advanced non-small cell lung cancer (aNSCLC): 3-year update from CheckMate 227 Part 1**

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**Introduction:** In CheckMate 227 Part 1 (NCT02477826), 1L NIVO+IPI significantly improved overall survival (OS) vs chemo in patients with aNSCLC and tumor PD-L1 ≥1% (primary analysis) or <1% (descriptive analysis). We report data with 3-year minimum follow-up.

**Methods:** Patients with stage IV/recurrent NSCLC and PD-L1 ≥1% (n=1189) were randomized to NIVO (3 mg/kg Q2W)+IPI (1 mg/kg Q6W), NIVO (240 mg Q2W), or chemo. Patients with PD-L1 <1% (n=550) were randomized to NIVO+IPI, NIVO (360 mg Q3W)+chemo, or chemo. Primary endpoint was OS with NIVO+IPI vs chemo in patients with PD-L1 ≥1%. An exploratory analysis was OS by response status (CR/PR, SD, progressive disease [PD]) at 6 months.

**Results:** After median follow-up of 43.1 months, patients with PD-L1 ≥1% had continued OS benefit from NIVO+IPI vs chemo (HR: 0.79; 95% CI, 0.67–0.93); 3-year OS rates were 33% (NIVO+IPI), 29% (NIVO), and 22% (chemo). At 3 years, 18%, 12%, and 4% of patients with PD-L1 ≥1% treated with NIVO+IPI, NIVO, and chemo, respectively, remained progression-free; 38%, 32%, and 4% of confirmed responders remained in response at 3 years. In patients with PD-L1 <1%, OS HR for NIVO+IPI vs chemo was 0.64 (95% CI, 0.51–0.81); 3-year OS rates were 34% (NIVO+IPI), 20% (NIVO+chemo), and 15% (chemo); 13%, 8%, and 2% of patients remained progression-free; 34%, 15%, and 0% of confirmed responders remained in response. Effect of CR/PR, SD, or PD at 6 months on subsequent OS in patients with PD-L1 ≥1% is shown (Table). Any-Grade/Grade 3–4 treatment-related AEs were observed in 77%/33% and 82%/36% of all patients treated with NIVO+IPI and chemo, respectively.

**Conclusions:** NIVO+IPI provided durable and long-term OS benefit vs chemo in 1L aNSCLC. Patients with PD-L1 ≥1% and had CR/PR at 6 months had marked OS benefit with NIVO+IPI. No new safety signals were identified for NIVO+IPI.

**Table. Exploratory Landmark Analysis of OS by Response Status at 6 Months in Patients With PD-L1 ≥1%\* (NIVO+IPI vs Chemo)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Patients alive at 6 months** | **Response status at** **6 months, %** | **Post-landmark 1-year OS rate, %** | **Post-landmark 2-year OS rate, %** | **Post-landmark** **3-year OS rate, %** |
| **NIVO+IPI (n = 295) vs****Chemo****(n = 306)** | CR or PR, 39 vs 25 | 90 vs 73 | 76 vs 51 | 70 vs 39 |
| SD, 14 vs 18 | 69 vs 54 | 45 vs 38 | 34 vs 33 |
| PD, 46 vs 58 | 44 vs 47 | 22 vs 25 | 19 vs 17 |

**\*** Results in PD-L1 <1% patients will be presented.